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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,933	11/01/2001	Jeong S. Lee	ACSC 60355 (2750)	5440

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GUNTHER O. HANKE, ESQ. FULWIDER PATTON LEE & UTECH
, LLP HOWARD HUGHES CENTER
6060 CENTER DRIVE, TENTH FLOOR
LOS ANGELES, CA 90045

EXAMINER

MCKANE, ELIZABETH L

ART UNIT PAPER NUMBER

1744

DATE MAILED: 08/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/002,933	Applicant(s) LEE ET AL.	
	Examiner Leigh McKane	Art Unit 1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5, 7-12, 14-24 and 26-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 7-12, 14-24 and 26-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

New Matter

1. The amendment filed 7 July 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: in claims 14, 27, and 32, the limitation “so that the electron-beamed balloon has a second rupture pressure equal to *or not greater than* the first rupture pressure” (italicized portion) is not supported by the disclosure.

Applicant is required to cancel the new matter in the reply to this Office Action.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 14, 27, and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As set forth above, the limitation “so that the electron-beamed balloon has a second rupture pressure equal to *or not greater than* the first rupture pressure” (italicized portion) is not supported by the disclosure.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-3, 5, 7-11, 14-19, 21-24, and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al (U.S. Patent No. 5,849,846) in view of Sun et al (U.S. Patent No. 5,728,748).

As to claims 1-3, 5, 7-9, 11, 14, 15, 21-24, and 26-29, Chen et al teaches a method of sterilizing medical device component wherein the component (e.g. dilation catheter tubing material for balloons and catheters) is irradiated with an electron beam (col.9, lines 21-45) so as to increase the burst strength, fatigue strength, and burst (i.e. rupture) pressure. *Note: As Chen teaches that the burst pressure (i.e. rupture pressure) is increased, then the second rupture pressure is not significantly less than the first rupture pressure. The mean burst pressure is taught to be 17-20 atm after irradiation (col.9, lines 41-45). Chen et al is silent as to whether the e-beam radiation sterilizes the component. However, Sun et al teaches that e-beam radiation at a dose of 2.5 Mrad is effective in sterilizing polymeric materials. As the component of Chen et al will have to eventually undergo sterilization before use and since it is fabricated from a polymeric material like the components of Sun et al, one of ordinary skill in the art would have found it obvious to use the e-beam sterilization of Chen et al to both improve the performance characteristics of the component and to sterilize the component.

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Although Chen et al does not disclose treating the component within a sealed, evacuated container, Sun et al teaches a method of sterilizing a medical implant wherein the implant is placed within an air-tight container, the container evacuated and then repressurized with an inert gas within a sealed chamber. As Sun et al discloses that removing oxygen from the environment of the implant is necessary to prevent oxidation of the implant, it would have been an obvious step in the method of Chen et al. See col.4, lines 58-65). Moreover, in doing so with the catheter of Chen et al, the step of evacuation would purge the oxygen/air from the interior of the catheter and the step of repressurizing the sealed container with an inert gas would fill the catheter of Chen et al with the inert gas.

With respect to claim 10, it would have been obvious to apply the e-beam radiation a sufficient number of times in order to achieve sterilization and strengthening of the catheter balloon.

6. Claims 12, 20, 30- 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al and Sun et al as applied to claims 1 and 27 above, and further in view of Lee et al (WO 99/13924).

With respect to claims 12, 30, and 31, Chen et al teaches that catheter balloons are formed of polymeric materials but does not disclose using a polyether block amide. Lee et al, however, teaches the known use of PEBAX, a polyamide/polyether polyester copolymer, for forming a catheter balloon having a wall thickness of 0.0102 to 0.0381 mm (page 10, lines 5-6). As any catheter balloon would necessarily have to undergo sterilization, it would have been obvious to use the method of Chen et al with Sun et al to both strengthen and sterilize the PEBAX catheter balloon of Lee et al.

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As to claims 20, 32, and 35, Chen et al with Sun et al fails to disclose that the balloon catheter is a stent delivery balloon catheter. However, Lee et al teaches a stent delivery balloon catheter comprising a stent which may be metallic. See page 10, lines 11-18. It would have been obvious to employ the method of the combination to sterilize assembled stent delivery systems as they must be in a sterile state before use. As to the limitation requiring that "sections of the balloon located directly underneath the stent are penetrated less by the electron beam than are sections of the balloon located at spaces in a wall of the stent," this is an inherent occurrence of radiation sterilization, as the balloon will be shadowed by the stent, regardless of whether the stent is metal or a non-metal.

Response to Arguments

7. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion


8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Tabata et al (U.S. Patent No. 5,444,103) teaches exposing PTFE to radiation in an inert atmosphere. Wu (U.S. Patent No. 6,203,551) discloses terminal sterilization of a catheter balloon and stent. Rangwalla et al (EP 490472) teaches e-beam irradiation of surfaces in an inert atmosphere.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Wednesday (7:15 am-4:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1275. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Leigh McKane
Primary Examiner
Art Unit 1744

elm
9 August 2004